17 CCR Section1230

§1230. Approval of Laboratories for Use of HIV Antibody Test.

(a) No person or entity shall perform tests to detect antibodies to HIV in California, or on specimens originating in California, unless that person or entity is

(1) licensed or certified:

(A) to engage in the production of biologics in accordance with chapter 4, division 2 of the Health and Safety Code, or

(B) as a clinical laboratory in accordance with chapter 3, division 2 of the Business and Professions Code, or

(C) as a public health laboratory in accordance with chapter 7, part 2, division 1 of the Health and Safety Code, or

(D) as a blood bank by the United States Food and Drug Administration in accordance with 42 U.S.C., section 262(a), or

(E) as a clinical laboratory licensed in serology to engage in interstate commerce in accordance with the Clinical Laboratory Improvement Act of 1967 (CLIA-67), 42 U.S.C. section 263a. and

(2) Enrolled in a proficiency testing program approved by the Department in accordance with Title 17, section 1051 of the California Code of Regulations for each HIV screening and confirmatory procedure offered by the laboratory.

(b) An application for approval shall be submitted for each separate location where tests are performed using forms provided by the Department and providing information as required by the Department. Within 15 days of receipt of an application, the Department shall notify the applicant in writing that the application is complete or shall specifically identify what additional information is required.

Within 60 days from the receipt of a completed application, the Department shall notify the applicant that the application is either approved or disapproved.

(c) An approved laboratory shall perform screening for evidence of human immunodeficiency virus (HIV) antibody utilizing only Food and Drug Administration (USFDA) approved kits. In addition, screening assays shall be performed in strict accordance with a kit's package insert and any other manufacturers' instructions or guidelines.

(d) A specimen shall not be reported as positive on the basis of a screening result. Approved laboratories shall perform confirmatory testing on all specimens tested which give a repeatedly-reactive HIV screening result using an additional more specific test prior to reporting the result.

(e) Whenever a confirmatory test gives an indeterminate result, the specimen giving such an indeterminate result shall be evaluated further, either by additional local testing or by referral to another laboratory. If, upon further evaluation the specimen continues to give an indeterminate result, the laboratory shall notify the submitter of the specimen that the result is inconclusive.

(f) An approved laboratory shall maintain records of tests and test results in a manner to ensure the patient's confidentiality.

(g) Approved laboratories which are blood banks or plasma centers shall report to the Department at the conclusion of each month and all other approved laboratories shall report to the Department at the conclusion of each quarter the number and results of the tests performed.

(h) Approval for performing the tests to detect antibodies to HIV may be denied or terminated for failure to comply with the requirements of this section or with requirements set forth in law, or for conduct inimical to the public health, morals, welfare, or safety of the people of the State of California in the maintenance and operation of the facility or services for which approval is granted.

NOTE

Authority cited: Sections 208 and 1603.1(h), Health and Safety Code. Reference: Section 5, Statutes of 1985, Chapter 23; and Sections 1603.1 and 1632, Health and Safety Code.

HISTORY

1. New section filed 1-21-86 as an emergency; effective upon filing (Register 86, No. 6). A certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 5-21-86.

2. Change without regulatory effect of group 9 and article 1 heading filed 2-7-86; effective upon filing (Register 86, No. 6).

3. Certificate of Compliance as to 1-21-86 order including amendment of section heading and subsections (b) and (f) transmitted to OAL 5-15-86 and filed 6-12-86 (Register 86, No. 24).

4. Amendment filed 1-8-90 as an emergency; operative 1-8-90 (Register 90, No. 4). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed by operation of law on 5-8-90.

5. Amendment filed 5-11-90 as an emergency; operative 5-11-90 (Register 90, No. 25). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed by operation of law on 9-8-90.

6. Amendment filed 9-12-90 as an emergency; operative 9-12-90 (Register 90, No. 43). A Certificate of Compliance must be transmitted to OAL by 1-10-91 or the emergency language will be repealed by operation of law on the following day.

7. Certificate of Compliance including amendment transmitted to OAL 1-9-91 and filed 2-8-91 (Register 91, No. 11).